

April 30, 1999

Dockets Management Branch, Food and Drug Administration, Department of Health and Human Services, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

The undersigned submits this petition under 21CFR 740.1, 740.2, 740.10 of the Federal Food, Drug, and Cosmetic Act for which authority has been delegated to the Commissioner of Food and Drugs under 21 CFR 5.10 to request the Commissioner of Food and Drugs to take administrative action.

Action requested:

The petitioner requests the Commissioner to take administrative action, and declare "Eternity" eau de parfume by Calvin Klein Cosmetics Company, Trump Tower, 725 Fifth Avenue New York NY 10022-2519 USA misbranded.

Statement of grounds:

21CFR Sec. 740.1 states : The label of a cosmetic product shall bear a warning statement whenever necessary or appropriate to prevent a health hazard that may be associated with the product.

21CFR Sec. 740.2 states: A warning statement shall appear on the label prominently and conspicuously as compared to other words, statements, designs, or devices and in bold type on contrasting background to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use, but in no case may the letters and/or numbers be less than 1/16 inch in height, unless an exemption pursuant to paragraph (b) of this section is established.

21CFR Sec. 740.10 Each ingredient used in a cosmetic product and each finished cosmetic product shall be adequately substantiated for safety prior to marketing. Any such ingredient or product whose safety is not adequately substantiated prior to marketing is misbranded unless it contains the following conspicuous statement on the principal display panel:

"Warning--The safety of this product has not been determined."

The perfume "Eternity" contains substances in which the chemical, physical, and toxicological properties have not been thoroughly investigated. Many of the substances in "Eternity" have known adverse effects on health. The packaging does not carry the required warning label. (See Attachment 1: PHOTO OF ETERNITY LABEL)

"Eternity" has been reported by consumers as having neurological and respiratory effects. (See FDA Consumer Complaints for Cosmetic Products 1995 Annual Report) Due to the trade secret status of fragrances fragrance ingredients are not listed on the label. This makes it extremely difficult to pinpoint substances in a fragrance that may trigger adverse reactions. Gas Chromatography studies are able to detect most of the materials in a fragrance. This testing is expensive and beyond the scope of most consumers. However, it is used routinely within the industry to develop and copy fragrance formulas.

Basis of identity of materials in Eternity:

Gas Chromatography studies were performed on "Eternity" by two different laboratories on two different samples that were sent in original packaging to the laboratories.

Laboratory 1:

The fragrance formula made up approximately 20% of the product with ethanol making up the remaining 80%. Due to limitations of the database available to the laboratory many of the materials were not identified with the required degree of accuracy.

(See Attachments: The Analysis of Perfumes and their Effect on Indoor Air Pollution John J. Mamura, Scientific Instrument Services, 1027 Old York Road, Ringoes, NJ 08551 Presented at EAS, Somerset, NJ, November 1998) and Index to Compounds in Perf

Diethyl Phthalate (CAS# 84-66-2) was positively identified as being present. Further study showed the temperature needed to volatilize Diethyl Phthalate was much higher than skin temperature. This indicates the compound would remain on the skin which would increase potential for absorption. With concerns over diethyl phthalate as a hormone disrupter, use in direct skin contact products, especially products that are used on a daily basis poses serious health concerns. Phthalates are known to be lipophilic in nature and have the potential to accumulate in fat tissue.

(See Attachment: The Estrogenic Activity of Phthalate Esters In Vitro; Catherine A. Harris, Pirkko Henttu, Malcolm G. Parker, and John P. Sumpter; Environmental Health Perspectives Volume 105, Number 8, August 1997)

Laboratory 2:

Laboratory 2 is a member of the Research Institute of Fragrance Materials and specializes in fragrance/flavors. All single raw materials presently known to the lab (ca. 2500) down to 0.1% are indicated. The percentages correspond to the area of the total ion count after integration. 43 individual substances were pinpointed. 41 of the 43 were identified, two substances were unknown.

(See Attachment: Analysis Report: Eternity)

Available safety data was obtained from chemical companies and other sources of information. Chemicals are sorted in descending order of prominence in the formula, Chemical Abstract Services numbers are provided. Information was not readily available on all materials. Attached reference material for each substance is indicated.

(See Attachment: ANALYSIS SUMMARY)

MSDS and other references materials are provided for individual substance in attachments

Discussion:

The physical, chemical, and toxicology properties of the individual substances used in this fragrance have not been thoroughly investigated. Some of the materials do have some data available. The Research Institute for Fragrance Materials (RIFM) has done testing and that information has been published in various issues of *Food and Chemical Toxicology*. In general testing by the RIFM pertains to effects on the skin and acute oral toxicity. Chronic effects are not generally tested, nor are neurological and respiratory effects. Copies of the RIFM material reports are included in the information on individual chemical.

Many fragrance materials are on the GRAS or Generally Recognized As Safe List. This designation pertains to substances considered safe for ingestion, and not for other routes of exposure. Further many substances that were in use in 1958 were given the GRAS status based on history of use. Very little actual safety testing had been conducted. GRAS is a designation based on industry experts. Not all GRAS substances have been affirmed by the FDA.

In the past using GRAS designation as a guideline for safety of a material used in fragrances has not protected the public's safety. Musk ambrette (CAS# 83-66-9) had been in use since before the 1920s. FEMA gave musk ambrette GRAS status in 1965. In a monograph published in 1975 musk ambrette was found to have neurotoxic properties. However, use as a flavor was generally below 1 ppm and thought not to pose any health risks at these levels. Later studies found musk ambrette was readily absorbed through the skin and slowly excreted. Levels used in fragrances were much higher than those used in flavors. Levels safe for GRAS status in foods did not ensure safety at the levels used in fragrances and did not take into account a different route of exposure. (See 1975: FCT, V13, p875)

Synthetic musk chemicals have been found to be lipophilic and accumulate in human fat tissue. Further synthetic musk chemicals have been found in breast milk. The long term effects are not known as few studies have been done. Any material that bioaccumulates in the tissues are of concern. The effects on fetal growth and development is not known. Synthetic musks often used at relatively high levels in a fragrance formula.

Neurological effects are another concern associated with synthetic musks. Several materials used in the past had serious neurological effects. The lack of neurological testing on synthetic musks is of concern since these materials are widely used at high levels in fragrance formulas. (See: Nitro musks in fragrance products: an update of FDA findings. Cosmetics and Toiletries, June 1996 (v111 n6) Start Page p73 (4) ISSN: 0361-4387 Wisneski, Harris S. Havery, Donald C.)

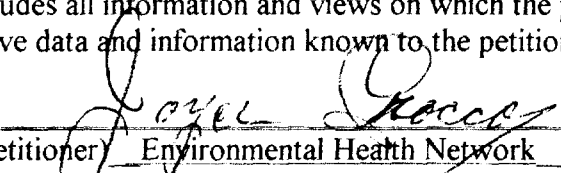
Summary:

The materials in Eternity have not been adequately tested for safety. There are legitimate concerns over the safety of the product. The product does not carry the required warning label. This petition respectfully requests the perfume "Eternity" be declared misbranded.

Environmental Impact: No environmental impact anticipated

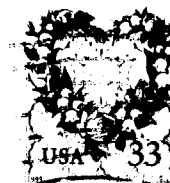
Certification:

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

(Signature) 
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